

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/053525

International filing date (day/month/year)
16.12.2004

Priority date (day/month/year)
17.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61K9/20

Applicant
PANTEC AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/EP2004/053525

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/053525

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-13 |
| | No: Claims | 14 |
| Inventive step (IS) | Yes: Claims | 1-13 |
| | No: Claims | 14 |
| Industrial applicability (IA) | Yes: Claims | 1-14 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/053525

Re Item V

Reasoned statement with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Cited Documents

The following documents are referred to in this communication:

- D1: US-A-4 371 516 (PEACH JAMES M ET AL) 1 February 1983 (1983-02-01)
- D2: US-A-5 976 577 (GREEN RICHARD ET AL) 2 November 1999 (1999-11-02)
- D3: WO 02/062152 A (SCHOONMAN ANNEMARIE ; CHMIEL OLIVER (CH);
NESTLE SA (CH); DARBYSHIRE J) 15 August 2002 (2002-08-15)

2. Novelty (Art. 33(2) PCT)

D1 (see example 1 on column 4) and D2 (see example 1 on columns 8 and 9) disclose a fast disintegrating tablet which is produced by freeze-drying an aqueous suspension comprising an active ingredient and excipients. As mentioned by the Applicant (see page 3, lines 21,22) these tablets obtained by a freeze-drying process have a similar porous structure as the tablets of the present invention. The subject-matter of claim 14 is therefore not new (Article 33(2) PCT).

3. Inventive Step (Art. 33(3) PCT)

D1 is considered as closest prior art. It discloses tablets which are prepared by dispensing into blister packs and freeze-drying a suspension comprising an active ingredient and appropriate excipients.

The process of claim 1 differs from D1 in that it uses a pressure of between normal pressure (1,01325 bar) and 100 bar instead of a vacuum pressure used in the freeze-drying process of D1.

The objective problem of claims 1-13 may therefore be regarded as an improved process

of manufacturing fast-disintegrating tablets which is less time-consuming and less energy-consuming than a process using a freeze-drying step (see page 7, line 5-10). The subject-matter of claims 1-13 therefore appears to meet the requirements of Article 33(3) PCT.

Claim 14 not being new also lacks inventive step (Article 33(3) PCT).

4. Industrial applicability (Art. 33(4) PCT)

Claims 1-14 satisfy the criterion of industrial applicability set forth in Article 33(4) PCT.